

COVID-19 Antibody Rapid Test || KEY CHARACTERISTICS

The test kit identifies the body's response to coronavirus after the onset of infection and gives a qualitative YES/NO result **within 10 minutes**. Implementing rapid screening for COVID-19 has huge time and cost savings when compared to laboratory screening and will help to control the spread of the virus by identifying infection rapidly and accurately.

- ✓ The test kit is CE marked for professional use.
- ✓ As well as whole blood, the cassette can also operate with serum or plasma samples.
- ✓ The test cassette will work with whole blood, plasma, or serum. Capillary blood is the easiest to obtain via a finger prick, however, venous blood obtained via venipuncture is also suitable. The type of sample will not affect the sensitivity or accuracy of the test.



COVID-19 Antibody Rapid Test || HOW DOES THE TEST CASSETTE WORK?

The test is a lateral flow immunoassay test and operates in a similar way to a pregnancy test. Embedded into the test strip are antibodies that bind to a COVID-19 specific biomarker, Immunoglobulin G (IgG), and another infection biomarker, Immunoglobulin M (IgM). When a sample (blood, serum, or plasma) is added to one end of the test, it flows along the test strip and interacts with these antibodies. If the patient has contracted COVID-19, the biomarkers in their blood will bind to the antibodies on the test strip, leaving a visible test line. If the patient does not have COVID-19, no biomarkers should be present in their blood and no test line will be visible. There are separate test lines for IgG and IgM and only one needs to be visible for a positive result.

COVID-19 Antibody Rapid Test || IS THE TEST SPECIFIC FOR COVID-19?

The IgG that the test detects is specific to COVID-19, so a positive result would indicate COVID-19 infection. Although the IgM is a more generalised antibody, its presence, combined with IgG and/or the common symptoms of COVID-19, would also indicate infection with the novel SARS-CoV-2 virus. The test can be used for primary and secondary diagnosis of COVID-19.


COVID-19 Antibody Rapid Test || HOW ACCURATE IS THE TEST?

The COVID-19 Colloidal Gold Immunoassay Testing Kit, IgG/IgM Combined, had a positive coincidence rate of 100%, a negative coincidence rate of 98.65%, a positive predictive value of 98.41%, a negative predictive value of 100%, a total coincidence rate of 99.26%, a paired chi-square test P-value ≥ 0.05 and a Kappa value = 0.9852. The statistical results show that the two reagents are consistent, that is, the test reagent is equivalent to the reagents of the same species on the market. The results of simultaneous detection of homologous serum and plasma, whole blood, and peripheral blood samples using the test reagents show that the test reagent has a positive coincidence rate of 100%, a negative coincidence rate of 100%, a total coincidence rate of 100%, a paired chi-square test P-value ≥ 0.05 and. Kappa consistency test Kappa value = 1.0, indicating that the results of homologous serum and plasma, whole blood, peripheral blood test are consistent.

COVID-19 Antibody Rapid Test || CERTIFICATIONS & ACCREDITATION

The COVID-19 Antibodies Rapid Test Kit IgG/IgM Combined is CE marked for professional use and is therefore a registered IVD device, according to the requirements in the In Vitro Diagnostic Medical Device Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998. The test kit holds a Certificate of Free Sale issued by United Kingdom Medicines and Healthcare Products Regulatory Agency (UK Medical Devices Regulations 2002 S.I. No. 618, as amended) and **therefore may be freely sold in all member states of the European Economic Area including the United Kingdom.** The COVID-19 test is CE marked for professional use and is therefore suitable and ready for use by a healthcare professional.

COVID-19 Antibody Rapid Test || DATA & COMPARISON

RAPID COVID-19 ANTIBODY TEST						
	Rapid SARS CoV-2-Antibody IVD SWISSCO GROUP	Acro 2019-nCoV IgG/IgM Antibody Rapid Test ACRO Biotech	Roche SARS-CoV-2 Rapid Antibody Test Roche	ACCU-TELL® Covid-19 Rapid Test AccuBiotech	SARS-CoV-2 Antibody Rapid Test Joinstar	Beright Covid-19 Antibody Rapid Test Lotus NL
Price	Upon request	12 EUR	9.38 EUR	7.16 EUR	6.45 EUR	4.76 EUR
Sensitivity (Positive coincidence rate)	100%	100%	99.03%	86.8%	94.48%	94.4%
Specificity (Negative coincidence rate)	98.65%	98%	98.65%	98.6%	99.26%	95.0%
Speed (minutes)	10	10	10-15	10	10-15	10
Country of manufacture	UK  MANUFACTURED IN UNITED KINGDOM	USA	Korea	China	China	China

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The COVID-19 Antibody Test Kit contains the following items:

- ✓ 1x COVID-19 Test Cassette
- ✓ 1x Retractable Lancet
- ✓ 1x Capillary Sampler
- ✓ 1x Buffer Solution
- ✓ 1x Disinfectant Wipe
- ✓ 1x Cotton Swab
- ✓ 1x Band Aid